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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,710	06/10/2005	Christel Thea Jorgensen	10334.204-US	6943

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EXAMINER	
BADR, HAMID R	

ART UNIT	PAPER NUMBER
1794	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,710	JORGENSEN ET AL.	
	Examiner	Art Unit	
	HAMID R. BADR	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,8,10 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,8,10 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 6, 8, 10 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the selection of the type of enzymes . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Case law holds that applicant's specification must be "commensurately enabling [regarding the scope of the claims]" *Ex Parte Kung*, 17 USPQ2d 1545, 1547 (Bd. Pat. App. Inter. 1990). Otherwise **undue experimentation** would be involved in determining how to practice and use applicant's invention. The test for undue experimentation as to whether or not all compounds within the scope of claims 6, 8, 10 and 13 can be used as claimed and whether claims 6, 8, 10 and 13 meet the test is stated in *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. Inter. 1986) and *In re Wands*, 8 USPQ2d 1400, 1404 (Fed.Cir. 1988). Upon applying this test to claims 6, 8, 10 and 13, it is believed that undue experimentation **would** be required because:

4. Level of skill in the art: Different lipolytic enzymes have different mechanisms and different hydrolysis products. Given the broad disclosure in the claims of lipolytic enzyme, one of skill in the art would not be able to make or use the invention.

5. The presence of Examples: The examples provided by the applicant has a limited showing with respect to the exact nature of the enzymes in question and hence the scope of the claims.

6. Level of Unpredictability: A limited showing with respect to lipotytic enzymes will encompass all enzymes regarding lipids. There is no way to predict what other lipolytic enzymes are concerned.

7. The quantity of experimentation: The quantity of experimentation is great given that while the claims read lipolytic enzyme, the specification discloses only a few specific types.

8. In the light of the above factors, it is seen that undue experimentation would be necessary to make an use the invention of claims 6, 8, 10 and 13.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 6, 8, 10, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clausen et al. (WO 98/26057; hereinafter R1) in view of Burdge et al. (2000; A method for the separation of phosphatidyl choline, triacylglecerol, non-esterified fatty acids and cholesterol esters from plasma by solid phase extraction) ,

Helmy et al. (1995, TLC derived data relating to the in vitro deacylation of phospholipids by various extracellular phospholipase A2 compared with the in vitro deacylation of endogenous substrate by the endogenous phospholipase A2 of various tissues; hereinafter R3) and Inoue et al. (US 4,567,046; hereinafter R4).

3. R1 gives details of the action of phospholipase A1, phospholipase A2 and phospholipase B. R1 teaches the reactions of phospholipases on phosphatidyl choline, phosphatidyl ethanolamine, and lysophosphatidyl choline. (page 12, line 10 to page 13, line 3). These reactions show that fatty acids are released by the action phospholipases.

4. R1 teaches how to assay the phospholipase by measuring the release of free fatty acids from lecithin in a buffer (page 26, lines 10-13).

5. R1 discloses that the phospholipase of the invention can be used in any application where it is desired to hydrolyze the fatty acyl group(s) of a phospholipid or lysophospholipid such as lecithin or lyso-lecithin. The phospholipase of the invention can be used in the preparation of dough, bread and cakes, e.g. to improve the elasticity of the bread or cake. Thus the phospholipase can be used in a process for making bread, comprising adding the phospholipase to the ingredients of a dough, kneading the dough and baking the dough to make the bread (page 45, lines 9-22). The phospholipase of the invention may also be used in bread improving additives, e.g. dough compositions, dough additives, dough conditioners, pre-mixes and similar preparations conventionally added to the flour and/or the dough during processes for making bread or other baked products to provide improved properties of bread or other

baked products (page 47, lines 11-17). R1 gives details of a formulation for European straight dough white bread and rolls (page 93, preparation of bread).

6. R1 is silent regarding the use of thin layer chromatography (TLC) in the assay of phospholipases.

7. R2 reports a method for separation of phosphatidylcholine, triacyglycerol, non-esterified fatty acids and cholesterol esters from plasma by solid phase extraction (title).

8. R2 teaches how to isolate the plasma lipid classes by TLC. R2 employs Silica Gel 60 TLC plate using a solvent system to develop the plates. After processing the plates; bands corresponding to triacylglycerols, cholesterol esters, and non-esterified fatty acids are detected. (Page 782, col. 2, Isolation of plasma lipid classes by TLC). Since the separation of fats and fatty acids by TLC is a very well known technique in the chemistry of fats and oils, the released fatty acids (due to the hydrolysis of ester bonds by the lipolytic activity as claimed in the instant application) can readily be detected (as presently claimed).

9. R2 is silent regarding the incubation of the phospholipase and the substrate while they are both placed on the TLC plate.

10. R3 discloses that the assay of phospholipase may be conducted when both the enzyme and the substrate are both placed on the TLC plate. R3 teaches that Silica G plates were developed sequentially in one dimension with two mobile phases. The first mobile phase being acetone transports the neutral lipids, including the fatty acids derived from the PLA deacylation (Page 370, col. 1, TLC procedure). The direct TLC assay was conducted by first applying the substrate to the plates and after drying, one

or more applications of the phospholipase preparations were used to cover the substrate. After air drying, the plates were developed (page 370, col. 2, lines 1-6).

11. Given that N-acyl phsphatidyl ethanolamine or N-acyl lysophosphatidyl ethanolamine and phosphatidyl choline are being used as substrates of the lipolytic enzymes, the lipolytic enzyme as presently claimed should be a phospholipase. At the same time, since the enzyme is more specific for N-acyl phosphatidyl ethanolamine or N-acyl lysophosphatidyl ethanolamine than phosphatidyl choline, it should be a phosphatase D.

12. R1, R2 and R3 are silent regarding the use of phospholipases in baking.

13. R4 discloses the incorporation of phospholipase A and phospholipase D in the bread dough. R4 discloses that phospholipase D is a well known enzyme which occurs in wheat flour with only low activity. R4 further adds that any phospholipase D that occurs in plants may be used in the invention. Phospholipase D is used in an amount of 100-5000 units per kg of wheat flour in breadmaking. (Col. 3, lines14-22).

14. R4 discloses that the bread produced according to their invention has a large volume and is suitably soft and its interior is characterized by a well stretched structure in film form. Additionally, the bread can be stored for a long period without undergoing much staling. (Col. 4, lines 8-13).

15. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use the teachings of R1 by implementing the detection methods as taught by R2 and R3 and ultimately selecting an enzyme to be incorporated into dough to improve the baking qualities of the dough and the baked bread as disclosed by

R4. One would do so to benefit from a phospholipase in baking (as taught by R1) by first screening for phospholipases by assaying the phopholipase (as taught by R1, R2 and R3) and finally choosing an enzyme to be used to improve dough and bread as taught by R4. Absent any evidence to contrary and based on the combined teachings of the cited references; there would be a reasonable expectation of success in screening and selecting a phospholipase (lipolytic enzyme) to be used in baking experiments.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:30 to 4:30 (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794